

Attorney Docket No.: DC0258US.NP  
Inventors: Supattapone and Deleault  
Serial No.: 10/553,591  
Filing Date: January 17, 2006  
Page 4

#### REMARKS

Claims 4-5 are pending in this application. Claims 4-5 have been rejected. Claim 4 has been amended. No new matter has been added by this amendment. Applicants are respectfully requesting reconsideration in light of the amendments to the claims and the following remarks.

#### I. Withdrawn Rejections

Applicants acknowledge the withdrawal of the rejections under 35 U.S.C. §§101 and 102.

#### II. Rejection of Claims Under 35 U.S.C. 112

Claims 4-5 have been rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description and enablement requirements. Page 3, ¶2 of the Office Action states:

Specifically, the limitation reciting, '...consisting of ribonucleic acid molecules enhance...', added in Applicant's response dated September 15, 2008, was not contemplated in the disclosure at the time the application was filed, and thus, is new matter.

Page 4, ¶2 of the Office Action further states:

In the instant case, since the specification does not provide evidence of even one absolute molecular structure of an RNA molecule responsible for enhancing amplification of Prp<sup>sc</sup>, Applicant's disclosure cannot possibly provide a meaningful method for making a composition consisting of only that RNA molecule which possesses the claimed characteristic.

Applicants respectfully disagree with this rejection. Applicants have presented evidence that RNA isolated from brain homogenates can enhance Prp<sup>sc</sup> amplification. See page 6, lines

Attorney Docket No.: DC0258US.NP  
Inventors: Supattapone and Deleault  
Serial No.: 10/553,591  
Filing Date: January 17, 2006  
Page 5

25-30. In addition, when this RNA was further fractioned by ultrafiltration and oligo-dT chromatography, the RNA that enhanced Prp<sup>Sc</sup> amplification was characterized as being polyA- and >300 nucleotides. See page 7, first full paragraph. Accordingly, to place the claims in better form for consideration, Applicants have amended claim 4 to specify that the composition consists of an ultrafiltration fraction of poly A<sup>-</sup>, >300 nucleotide ribonucleic acid molecules, which enhances the amplification of PrP<sup>Sc</sup>. Support for this amendment is found in claim 1 as originally filed, at pages 6 and 7 of the specification and Example 6 at page 20. In so far as the RNA fraction of the disclosure is substantially free of contaminants (see page 8, lines 15-17), Applicants disclosure fully supports the RNA composition as claimed. Therefore, it is respectfully requested that the rejection of the claims under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn.


### **III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: **DC0258US.NP**  
Inventors: **Supattapone and Deleault**  
Serial No.: **10/553,591**  
Filing Date: **January 17, 2006**  
Page 6

favorable reconsideration and subsequent allowance of the  
pending claim is earnestly solicited.

Respectfully submitted,



Jane Massey Licata  
Registration No. 32,257

Date: **March 24, 2009**

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515  
Email: JMLicata@licataandtyrrell.com